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ROBINS & PASTERNAK
1731 EMBARCADERO ROAD
SUITE 230
PALO ALTO, CA 94303

EXAMINER

COLLINS, CYNTHIA E

ART UNIT PAPER NUMBER

1638

DATE MAILED: 05/09/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/732,348

Applicant(s)

CHOO ET AL.

Examiner

Cynthia Collins

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Jan. 17, 2003, June 24, 2003, May 26, 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 24-70 is/are pending in the application.
- 4a) Of the above claim(s) 30, 31, 43 and 51-70 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 24-29, 32-42 and 44-50 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

The amendments filed January 17, 2003, June 24, 2003 and May 26, 2004 have been entered.

In the amendment filed January 17, 2003, claims 1-23 were cancelled. Claims 24-70 were newly added.

In the amendment filed June 24, 2003, claims 26, 27, 29, 53, 54 and 56 were amended.

In the amendment filed May 26, 2004, claims 25 and 52 were amended.

Claims 24-70 are pending.

Claims 43 and 51-70 are withdrawn.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

All previous objections and rejections not set forth below have been withdrawn.

Supplemental Election/Restrictions

Applicant's election with traverse of Group A, claims 24-29, 32-42 and 44-50, in the reply filed on January 31, 2005 is acknowledged.

The traversal is on the ground(s) that it is improper to issue yet another Restriction Requirement when there is currently a Petition for Withdrawal of a previous Restriction Requirement awaiting decision.

This is not found persuasive because the Petition for Withdrawal of a previous Restriction Requirement was decided February 9, 2004, and the outstanding Restriction Requirement was mailed December 28, 2004.

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The traversal is also on the ground(s) that the outstanding Restriction Requirement improperly restricts as between engineered zinc finger proteins comprising one or more zinc finger proteins (Group A) and engineered zinc finger proteins in which it is specified that one or more of the zinc fingers comprise a mutated model zinc finger domain (Groups B to E).

Applicants maintain that there is no factual or legal basis for distinguishing between "engineered" zinc finger domains and "mutated model" zinc finger domains because all of the zinc finger proteins are engineered, whether by selection, design or mutation. Simply put, mutated model zinc finger domains are a subset of engineered zinc finger domains.

This is not found persuasive because the mutated model zinc finger domains of Groups B-E differ from the engineered zinc finger polypeptide of Group A. Specifically, the inventions of Groups B-E require a separate area of search directed to one or more of the zinc fingers of an engineered zinc finger polypeptide comprising a mutated model zinc finger domain, which search is not required for the invention of Group A. Further, each of inventions of Groups B-E requires an additional separate area of search directed to specific mutated model zinc finger domain corresponding to a distinct type of zinc finger protein (Zif268, GLI, Tramtrack and YY1) that originates from one of several different species of organisms (human, mouse, *Drosophila*).

The traversal is additionally on the ground(s) that all Groups share the same classification and sub classification, and that therefore, no serious burden is imparted on the Examiner if the Groups are searched together.

This is not found persuasive because the search and examination of the different Groups of invention is not limited to a search of class and subclass exclusively.

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The traversal is further on the ground(s) that that restriction between members of a Markush Group (in this case, between different zinc finger proteins as the source of the mutated zinc finger domain) is improper (see, MPEP 803.02).

This is not found persuasive because the members of the Markush group are not sufficiently few in number or so closely related that a search and examination of the entire claim can be made without serious burden.

The traversal is also on the ground(s) that it is improper for the Office to refuse to examine that which applicants regard as their invention, unless the subject matter in a claim lacks unity of invention. In this regard Applicants maintain that the allegedly distinct zinc finger proteins from which mutated zinc finger domains may be derived share a common utility (namely, DNA binding) and a substantial structural feature disclosed as being essential to that utility (namely, a zinc finger domain).

This is not found persuasive because the zinc finger proteins recited in the claims comprise different types of zinc finger domains (Zif268, GLI, Tramtrack and YY1).

Accordingly, claims 30-31 are withdrawn as being directed to nonelected inventions.

The requirement is still deemed proper and is therefore made FINAL.

Claim Rejections - 35 USC § 112

Claims 24-29, 32-42 and 44-50 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the

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application was filed, had possession of the claimed invention, for the reasons of record set forth in the office action mailed October 23, 2002.

Applicants' arguments filed January 17, 2003 have been fully considered but they are not persuasive.

Applicants maintain that the test for whether there is an adequate written description is whether the application as filed evinces possession of the claimed subject matter by Applicants. In this regard Applicants point to the numerous documents of record and the disclosure, particularly pages 8-19, page 28, pages 50-51 and Example 5. Applicants maintain that there was clearly possession of the claimed subject matter at the time of filing, and that there is clearly a written description of the claimed subject matter in the present application. (pages 14-15 of the reply filed January 31, 2005)

The Examiner maintains that the claimed invention is not adequately described. As for the numerous documents of record and the disclosure, the Examiner maintains that Applicants' disclosure of the state of the art with respect to zinc finger polypeptides does not serve to describe what Applicants have invented. In this regard the Examiner maintains that Applicants' description of a plant host cell or transgenic plant comprising a polynucleotide of SEQ ID NO:4 encoding a fusion of four fingers of a TFIIIA zinc finger polypeptide, three fingers of a Zif268 zinc finger polypeptide, and a VP16 or VP64 transcriptional activator domain, and a polynucleotide comprising one or four heterologous target sequences of SEQ ID NO:7 operably linked to a heterologous GFP or RFP coding sequence whose transcription is regulated by binding of the zinc finger polypeptide to the target sequence does not constitute an adequate description of a substantial portion of the claimed genus that encompasses plant cells and plants

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comprising polynucleotides encoding any unspecified zinc finger polypeptide engineered in any unspecified manner and any unspecified target DNA sequence to which the zinc finger polypeptide binds, plant cells and plants comprising polynucleotides encoding zinc finger polypeptides having any unspecified combination of two or more, or more than three, zinc fingers of the formula $X_{0-2} C X_{1-5} C X_{9-14} H X_{3-6} H/C$, and plant cells and plants comprising polynucleotides encoding zinc finger polypeptides having any unspecified combination of or four, five, six, seven, eight or nine zinc fingers of the formula $X_{0-2} C X_{1-5} C X_{9-14} H X_{3-6} H/C$.

The Examiner also maintains that evincing possession of the claimed subject matter by Applicants is not the sole test for whether there is an adequate written description.

See Enzo Biochem Inc. v. Gen-Probe Inc., 63 USPQ2d 1609, 1617:

Application of the written description requirement, however, is not subsumed by the “possession” inquiry. A showing of “possession” is ancillary to the *statutory* mandate that “[t]he specification shall contain a written description of the invention,” and that requirement is not met if, despite a showing of possession, the specification does not adequately describe the claimed invention. After all, as indicated above, one can show possession of an invention by means of an affidavit or declaration during prosecution, as one does in an interference or when one files an affidavit under 37 C.F.R. § 1.131 to antedate a reference. However, such a showing of possession alone does not cure the lack of a written description in the specification, as required by statute.

In the instant case the specification does not adequately describe the claimed invention.

Claim 1, and claims 25-29, 32-42 and 44-50 dependent thereon, are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention, for the reasons of record set forth for claims 7-8 in the office action mailed October 23, 2002.

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Applicants' arguments filed January 17, 2003 have been fully considered but they are not persuasive.

Applicants point to page 3, lines 15-17, page 4, line 22 to page 5, line 3, and page 9, lines 14-17 of the specification where the term "engineered" is discussed (page 13 of the reply filed January 17, 2003).

The Examiner maintains that the discussion of "engineered" set forth at page 3, lines 15-17, page 4, line 22 to page 5, line 3, and page 9, lines 14-17 of the specification does not limit the term "engineered" in claim 24. Accordingly it is still unclear in what way the zinc finger polypeptide is "engineered", as a polypeptide may be engineered in many different ways, such as by cloning of the polynucleotide that encodes the polypeptide, by mutating the cloned polynucleotide that encodes the polypeptide, by fusing the cloned polynucleotide with polynucleotides that encode other polypeptides, etc.

Claim 25, and claims 26-29, 32-34, 40-42 and 45-48 dependent thereon, are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 25 is indefinite in the recitation of "two or more". It is unclear how many zinc fingers the polypeptide has, as "two or more" places no upper limit on the number of zinc fingers the polypeptide may have, and a polypeptide would not have an infinite number of zinc fingers.

Claim 25, and claims 26-29, 32-34, 40-42 and 45-48 dependent thereon, are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 25 is

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indefinite in the use of parentheses. It is unclear whether the parenthetical is intended to limit the claim. It is suggested that the parentheses be deleted in order to overcome the rejection.

Claim 26, and claims 27-29 dependent thereon, are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 26 is indefinite in the use of parentheses. It is unclear whether the parenthetical is intended to limit the claim. It is suggested that the parentheses be deleted in order to overcome the rejection.

Claim 27 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 27 is indefinite in the use of parentheses. It is unclear whether the parentheticals are intended to limit the claim. It is suggested that the parentheses be deleted in order to overcome the rejection.

Claim 28 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 28 is indefinite in the recitation of "one or more". It is unclear how many zinc fingers would bind to a target DNA, as "one or more" places no upper limit on the number of zinc fingers the polypeptide may have, and a polypeptide would not be expected to have an infinite number of zinc fingers bind to a target DNA.

Claim 29 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 29 is indefinite in the use of parentheses. It is unclear whether the

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parenthetical is intended to limit the claim. It is suggested that the parentheses be deleted in order to overcome the rejection.

Claim 32 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 32 is indefinite in the recitation of “more than three”. It is unclear how many zinc fingers the polypeptide has, as “more than three” places no upper limit on the number of zinc fingers the polypeptide may have, and a polypeptide would not have an infinite number of zinc fingers.

Claim 48 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention, for the reasons of record set forth for claims 14 and 21 in the office action mailed October 23, 2002

Applicants’ arguments filed January 17, 2003 have been fully considered but they are not persuasive.

Applicants point to page 6, lines 6-9 of the specification as defining “biological effector domain”(page 13 of the reply filed January 17, 2003).

The Examiner maintains that the definition of “biological effector domain” set forth in the specification at page 6, lines 6-9 does not limit the term “biological effector domain” in claim 48. Accordingly it is still unclear what biological property is affected by the effector domain, as a polypeptide domain may affect many different types of biological properties, such as transcription, translation, phosphorylation, etc.

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Claim Rejections - 35 USC § 102

Claims 24, 35-36, 38, 39, 44 and 49-50 are rejected under 35 U.S.C. 102(b) as being anticipated by Aoyama T. et al. (A glucocorticoid-mediated transcriptional induction system in transgenic plants. Plant J. 1997 Mar;11(3):605-12), for the reasons of record set forth for claims 7-8, 10-11, 13-15, 17-18 and 20-22 in the office action mailed October 23, 2002.

Applicants' arguments filed January 17, 2003 have been fully considered but they are not persuasive.

Applicants point out that the claims recite an "engineered" zinc finger polypeptide, and maintain that, in contrast to the meaning of "engineered" set forth in the specification, the putative zinc finger portion of Aoyama's fusion comprises a naturally-occurring GAL4 zinc finger polypeptide, such that Aoyama fails to teach or suggest an engineered zinc finger polypeptide as disclosed in the present application. (page 21 of the reply filed January 31, 2003)

The Examiner maintains that the discussion of "engineered" set forth in the specification does not limit the term "engineered" in claim 24. Accordingly Aoyama et al. anticipate the rejected claims because the GAL4 zinc finger polypeptide of Aoyama et al. is genetically engineered.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

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Claims 24-25, 32-33, 35-37, 39, 44 and 46-50 are rejected under 35 U.S.C. 102(e) as being anticipated by Cox et al. (US Patent No. 6,534,261, issued March 18, 2003, filed January 12, 1999).

The claims are drawn to a plant host cell or transgenic plant comprising a polynucleotide encoding an engineered zinc finger polypeptide and a target DNA sequence to which the zinc finger polypeptide binds, wherein the target DNA is part of an endogenous sequence and is operably linked to a coding sequence, including a plant host cell or transgenic plant wherein the zinc finger polypeptide has two or more zinc fingers and the zinc fingers structures of the formula $X_{0-2} C X_{1-5} C X_{9-14} H X_{3-6} H/C$, including a plant host cell or transgenic plant wherein the zinc finger polypeptide has six zinc fingers, including a plant host cell or transgenic plant wherein the zinc finger polypeptide is fused to a biological effector or transcriptional activator domain, including a VP16 or VP64 transcriptional activator domain.

Cox et al. teach a plant host cell or transgenic plant comprising a polynucleotide encoding an engineered zinc finger polypeptide and a target DNA sequence to which the zinc finger polypeptide binds, wherein the target DNA is part of an endogenous sequence and is operably linked to a coding sequence, including a plant host cell or transgenic plant wherein the zinc finger polypeptide has two or more zinc fingers and the zinc fingers structures of the formula $X_{0-2} C X_{1-5} C X_{9-14} H X_{3-6} H/C$, including a plant host cell or transgenic plant wherein the zinc finger polypeptide has more than three or six zinc fingers, including a plant host cell or transgenic plant wherein the zinc finger polypeptide is fused to a biological effector or transcriptional activator domain, including a VP16 or VP64 transcriptional activator domain (columns 75-79 claims 1-10, 30-39, 46, 59, 63-68; column 1 line 55 through column 2 line 4;

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column 2 lines 43-50; column 7 line 66 through column 7 line 7; column 9 lines 28-39; column 9 line 61 through column 10 line 9; column 10 lines 24-44; column 13 lines 21-30; column 15 lines 7-24; column 22 lines 8-13; column 24 lines 14-17; column 35 line 40 through column 37 line 53).

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Remarks

No claim is allowed.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cynthia Collins whose telephone number is (571) 272-0794. The examiner can normally be reached on Monday-Friday 8:45 AM -5:15 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson can be reached on (571) 272-0804. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Cynthia Collins
Examiner
Art Unit 1638

CC

Cynthia Collins 5/2/05